

## **REMARKS**

### ***Response to Restriction Requirement***

The Restriction Requirement required restriction to one of Groups I, II, III, IV, V, and VI all of which purportedly do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature.

Applicant hereby provisionally elects **Group II** (claims 17-32), drawn to a method for treating brain injury, damage or disease comprising administering a GALR2-specific small, non-peptide chemical entity **with traverse**. Applicant reserves the right to file divisional application(s) directed to non-elected subject matter.

Applicant respectfully requests reconsideration of the restriction requirement in view of the following remarks.

According to PCT Rule 13.2, unity of invention exists between groups of inventions when there is a technical relationship among the claimed inventions involving one or more of the same corresponding special technical features.

The Restriction Requirement asserts that Groups I, II, III, IV, V, and VI do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features. In particular, the Restriction Requirement asserts that "GALR2-specific agonist compounds and their use in the treatment of brain injury, damage or disease" is allegedly disclosed by Liu, *et al.* (August 14, 2001) PNAS ("Liu"). The Restriction requirement asserts that Liu discloses "the use of GALR2-specific agonists, and the AR-M1896 peptide of the instant claims, for [*in vivo*] treatment of neuropathic pain or nociception" and thus teaches the special technical feature of claim 1. Restriction Requirement at page 3.

Applicants respectfully disagree. At least one special technical feature of claim 1 is the use of GALR2-specific agonist compounds and their use in the treatment of brain injury, damage or disease as described in claim 1. This special technical feature is shared by all six Groups. Indeed, Group I is drawn to a method for treating brain injury, damage or disease comprising administration of a GALR2-specific agonist polypeptide; Group II is drawn to a method for treating brain injury, damage or disease comprising administration of a GALR2-specific small, non-peptide chemical entity; Group III is drawn to a method of screening for a GALR2-specific agonist polypeptide; Group IV is drawn to a pharmaceutical composition comprising a GALR2-

specific agonist polypeptide; Group V is drawn to a pharmaceutical composition comprising a GALR2-specific non-peptide chemical entity; and Group VI is drawn to a method of inhibiting the death of a cell comprising contacting the cell with a GALR2-specific agonist. Thus all six groups encompass use of GALR2-specific agonist compounds and their use in the treatment of brain injury, damage, or disease.

Liu is silent on the technical feature of claim 1. In particular, Liu discusses the use of a GALR2-agonist in the spinal cord for the treatment of neuropathic pain does not discuss treating brain injury, damage, or disease comprising administering a GALR2-specific agonist. Rather, Liu discloses the analgesic effects of AR-M1896 and AR-M961 and is silent on the claimed uses of treating brain injury, damage, or disease comprising administering a GALR2-specific agonist. *See* Figure 2. Accordingly, Liu does not teach the special technical feature of claim 1.

Since the special technical feature shared by Groups I, II, III, IV, V, and VI are novel, there is no lack of unity. Rejoinder of Groups I, II, III, IV, V, and VI and examination of claims 17-100 is respectfully requested.

### *Species Election*

The Restriction Requirement requires that Applicant elect one of the allegedly distinct species as listed in claims 18-22 (*e.g.*, brain disease (*e.g.*, Alzheimer's Disease, Parkinson's Disease, Multiple Sclerosis, or variant Creutzfeld Jacob Disease) and brain injury or damage caused by embolic, thrombotic or haemorrhagic stroke direct or indirect trauma or surgery to the brain or spinal cord; ischaemic or embolic damage to the brain during cardiopulmonary bypass surgery or renal dialysis; reperfusion brain damage following myocardial infarction; brain disease; immunological damage (*e.g.*, bacterial or viral infection), chemical damage (*e.g.*, excess alcohol consumption or administration of chemotherapy agents for cancer treatment) or radiation damage (*e.g.*, radiotherapy). Applicant provisionally elects **MULTIPLE SCLEROSIS** (claims 17-32) **with traverse**.

The Restriction Requirement did not elucidate reasons and examples as required by MPEP § 808.02 to support a species election between the brain injury, brain damage, and brain disease as listed in claims 18-22. MPEP § 806.04(b). A requirement for restriction is permissible if there is a patentable difference between the species as claimed and there would be a serious burden on the Examiner if restriction was not required. MPEP § 808.01(a) [R-5].

In the election of species requirement, all of the damage, disease, and injury cause cell death in the brain (*e.g.*, same organ.) In particular, the brain diseases listed in claim 22 (*e.g.*, Alzheimer's Disease, Parkinson's Disease, Multiple Sclerosis, or variant Creutzfeld Jacob Disease) are all neurodegenerative disorders and thus are members of the same class of brain diseases. Accordingly, they are in the same classification, they do not occupy a separate status in the art from one another, and they share the same field of search. Therefore it is inappropriate to restrict between the listed types of brain disease, brain damage, and brain injury in claims 18-22.

In view of the above remarks, Applicants respectfully request that the Restriction Requirement be withdrawn and that all of the species in claims 17-32 be prosecuted in the same patent application. In the event that the requirement is made final and in order to comply with 37 C.F.R. § 1.143, Applicant reaffirms the election of **GROUP II** (claims 17-32) and the species election of **MULTIPLE SCLEROSIS** (claims 17-32) **with traverse**.

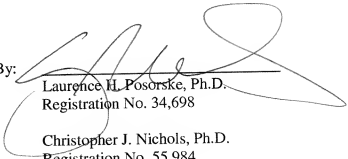
**CONCLUSION**

An indication of allowance of all claims is respectfully solicited. Early notification of a favorable consideration is respectfully requested.

Respectfully submitted,

Dated: June 5, 2009

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